JUN 2 9 2005

K050441 (pg 1 of 2)

BIOMET INC

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Kacy Arnold, RN, MBA
Regulatory Specialist

Proprietary Name: Taper 2™ Porous Femoral Stem

Common Name: Femoral Hip Stem

Classification Name: The Taper 2™ Porous Femoral Stems included in this submission have the following classification:

1. Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR §888.3358), Product Code: LPH
2. Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR §888.3358), Product Code: MBL

The mating components (modular heads and acetabular shells/liners) for use with the Taper 2™ Porous Femoral Stems have the following classifications:

1. Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR §888.3310), Product Code: KWZ
2. Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis (21 CFR §888.3320), Product Code: JDL
3. Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis (21 CFR §888.3330), Product Code: KWA
4. Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR§ 888.3350), Product Code: JDI
5. Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR §888.3353), Product Code: LZO
6. Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR §888.3353), Product Code, MEH
7. Hip joint metal/polymer/metal semi-constrained, porous-coated, uncemented prosthesis (21 C.F.R. §888.3358), Product Code: LPH
8. Hip joint metal/polymer/metal semi-constrained, porous-coated, uncemented prosthesis (21 C.F.R. §888.3358), Product Code: MBL
9. Hip joint (hemi-hip) acetabular metal cemented prosthesis, (21 CFR §888.3370), Product Code: KWB

K050441 (pg 2 of 2)

10. Hip joint (hemi-hip) acetabular metal cemented prosthesis (21 CFR §888.3370), Product Code: LZY
11. Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR§888.3390), Product Code: KWY

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

TaperLoc® Porous and Reduced Distal Femoral Stems – Biomet (K921301)
Mayo® Conservative Hip Prosthesis – Zimmer Inc. (K943230)

Device Description: The Taper 2™ Porous Femoral Stem is a short, tapered stem, designed to provide rotational stability for long-term fixation and physiologic proximal load transfer for bone preservation.

Indications for Use: Taper 2™ Porous Femoral Stems

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis
3. Correction of functional deformity
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed femoral head resurfacing component.

The Taper 2™ Porous Femoral Stems are intended for non-cemented use only.

Summary of Technologies: The Taper 2™ Porous Femoral Stems are made of the same materials and utilize the same manufacturing, packaging and sterilization processes as the predicate devices. Testing determined that the stems are substantially equivalent to the predicate stems.

Non-Clinical Testing: Reference literature and performance data demonstrate that the Taper 2™ Porous Femoral Stems are substantially equivalent to the predicate femoral hip stems.

All trademarks are property of Biomet, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2005

Ms. Tracy Bickel Johnson, RAC
Manager of Regulatory Affairs
Biomet Manufacturing Corporation
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K050441
Trade/Device Name: Taper 2™ Porous Femoral Stem
Regulation Number: 21 CFR 888.3358, 888.3310, 888.3320, 888.3330, 888.3350, 888.3353, 888.3370, 888.3390
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated, uncemented prosthesis; Hip joint metal/polymer constrained cemented or uncemented prosthesis; Hip joint metal/metal semi constrained, with a cemented acetabular component, prosthesis; Hip joint metal/metal semi-constrained, with an uncemented acetabular component; Hip joint metal/ polymer semi-constrained cemented prosthesis; Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis; Hip joint (hemi-hip) acetabular metal cemented prosthesis; Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.
Regulatory Class: III
Product Code: LPH, MBL, KWZ, JDL, KWA, JDI, LZO, MEH, KWB, LZY, KWY
Dated: May 26, 2005
Received: May 27, 2005

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050441

Device Name: Taper 2™ Porous Femoral Stem

Indications For Use:

The Taper 2™ Porous Femoral Stem is indicated for use in patients requiring total hip replacement due to the following:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques
- Revision of previously failed femoral head resurfacing component

Taper 2™ Porous Femoral Stems are intended for uncemented use only.

Specific indications for compatible components that can be used with the above femoral stems include:

Constrained Liners (K030047)

Constrained liners are intended for general use in skeletally mature individuals undergoing primary and/or revision surgery at high risk of hip dislocation due to history of prior dislocation, joint or bone loss, soft [tissue] laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered.

OSS / Salvage Systems / Total Femur (K974558, K002757, K021380, K033871)

Salvage/Oncology Hip and Total Femur components are also indicated for cases of ligament deficiency, tumor resection, trauma and revision of unsuccessful osteotomy or arthrodesis.

Interlocking Stems (K990830, K042774)

Interlocking hip stems are indicated for non-cemented application in cases of revision, trauma, fracture, oncology or other situations where severe proximal bone loss may compromise the fixation and stability of a standard type hip replacement prosthesis.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050441